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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,114	06/22/2001	Seung-Ho Choi	19916-003001	9054
<div>26161 7590 05/16/2007 FISH &amp; RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022</div> <div>EXAMINER LUCAS, ZACHARIAH</div> <div>ART UNIT PAPER NUMBER 1648</div> <div>MAIL DATE DELIVERY MODE 05/16/2007 PAPER</div>				

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/888,114	<b>Applicant(s)</b> CHOI ET AL.	
	<b>Examiner</b> Zachariah Lucas	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2,3,5,12,14-22 and 42 is/are pending in the application.
- 4a) Of the above claim(s) 6-11 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,3,5,12,14-22 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 2, 3, 5-22, and 42 are pending in the application.
2. In the prior action, mailed on September 14, 2006, claims 2, 3, 5-22, and 42 were pending; with claims 2, 3, 5, 12, 14-22, and 42 under consideration and rejected; and claims 6-11, and 13 withdrawn as to non-elected inventions.
3. In the Response of March 13, 2007, the Applicant amended claims 2 and 5.
4. Claims 2, 3, 5, 12, 14-22, and 42 are currently under consideration.

### *Claim Objections*

5. **(Prior Objection- Withdrawn)** Claim 5 was objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. In view of the amendment of the claim, the objection is withdrawn.
6. **(New Objection)** Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 3 depends from claim 2. Claim 2 reads on a composition "consisting" of "a biopolymer." However, claim 3 purports to further limit the claim to embodiments comprising combinations of identified polymers. It is suggested that claim 2 be amended to read "at least one biopolymer."

Art Unit: 1648

7. **(New Objection)** Claim 42 is objected to because of the following informalities: the claim depends from a rejected claim. It is suggested that the claim be amended to depend from claim 2.
8. Appropriate correction is required.

***Double Patenting***

9. **(Prior Rejection- Withdrawn)** Claims 2, 3, 5, 12, 14-22, and 42 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8-11, 14-21, 24, 31, and 32-34 of U.S. Patent No. 6,248,360. In view of the Terminal Disclaimer submitted on March 13, 2007, the rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **(Prior Rejection- Restated and Maintained)** Claims 2, 3, 5, 12, 14-22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Scott et al., U.S. Patent 6,458,287, in view of Watts. Applicant traverses this rejection on the basis that the claims have been amended to exclude embodiments where additional complexing agents to the metal cation are present in the composition, and because the Scott reference teaches that the macromolecule complexing agents are required for the incorporation of compounds not having a tertiary structure into the polymeric

Art Unit: 1648

microparticles. In view of these arguments, the rejection is restated as a rejection of claims 2, 3, 5, 12, 14-22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Scott in view of Watts, and further in light of the teachings of Noble (U.S. 4,574,152), Voser (U.S. 3,725,400), and Chromecek (U.S. 3,886,125). In view of the restatement, Applicant's arguments are not found persuasive.

As indicated above, Applicant argues that the Scott reference indicates that the presence of a macromolecule is required for the incorporation of small-molecule drugs into the described particles. However, it is noted that the reference does not state that the macromolecules are required. Rather, the reference indicates that such small molecules “**can** be formed into a microsphere by incorporation or coupling of the compound to a carrier molecule that has a tertiary structure” (emphasis added). As was previously noted in the action of March 14, 2003 (page 8), the Scott reference also teaches that the metal cations are also complexing agents that are capable of interacting with therapeutic agents. Thus, those of ordinary skill in the art would have understood that the use of these agents would be an alternative to the use of the macromolecular complexing agents. Further, other teachings in the art indicate that the mere incorporation of such metals into a polymer matrix permits the entrapment of therapeutic agents, including antimicrobials and antibacterials, into the matrix. See e.g., Chromecek, column 7, lines 41-50. Further, other teachings in the art specifically teach that cephalosporins form complexes with certain metals. See e.g., Noble, column 1 lines 44-48; and Voser, column 5 lines 5-16. From these teachings, those of ordinary skill in the art would have had a reasonable expectation that the incorporation of the metal cation complexing agents would have been sufficient for the incorporation of at least cephalosporin based antibiotics into the microparticles.

While the Scott reference teaches the additional inclusion of the macromolecule complexing agents, because the additional teachings in the art indicate that such would not be required for the incorporation of a cephalosporin into the complex, it would have been obvious to those of ordinary skill in the art to leave such out of the particles. See e.g., Scott, column 6, lines 47-54 (indicating that active agents can be loaded into microspheres that lack complexing agents- suggesting to those of ordinary skill in the art that unnecessary components may be omitted). See also, MPEP § 2144.04 II.A (indicating that omission of an element and its function is obvious if the function of the element is not desired). Because the additional teachings of Chromecek, Noble, and Voser indicate that the presence of the metal cation would be sufficient to incorporate cephalosporins, it would have been obvious to those of ordinary skill in the art to leave out the macromolecule complexing agent. The combined teachings of the cited references therefore render the claimed inventions obvious.

The rejection is therefore maintained for the reasons above, and the reasons of record.

12. **(Prior Rejection- Restated and Maintained)** Claims 2, 3, 5, 12, 14-22, and 42 were rejected under 35 U.S.C. 103(a) as being unpatentable over Scott in view of Watts as applied to claims 2, 3, 5, 12, 14-22 above, and further in view of Horwitz et al. (U.S. 5,783,561). In view of the amendments to the claims as described above, this rejection is also restated as a rejection of claims 2, 3, 5, 12, 14-22, and 42 as being unpatentable over Scott in view of Watts and Horwitz, and further in view of Noble, Voser, and Chromecek. The Applicant traverses this rejection on the same basis as indicated with respect to the rejection immediately above. The arguments are not found persuasive in view of the restatement of the rejection as was also described above.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

#### *Conclusion*

14. No claims are allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

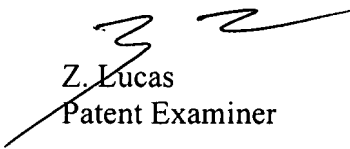
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1648

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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